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Remarks:

Claims 1-21 were pending in this application. In the Office Action mailed September 29, 2003, the Office rejected claims 1-21. With the present Response, Applicant cancels claim 14, amends claims 1-13 and 15-21, and adds new claims 22-30. Upon entry of the present amendment, claims 1-13 and 15-30 are pending.

Claim Objections

The Office objects to claims 1-21 for reciting inappropriate range expressions in each of claims 1, 18, and 21. In response, Applicant has amended the identified claims to correct the range expressions and respectfully requests the withdrawal of the objections.

Claim Rejections - 35 U.S.C. § 103

The Office rejects claims 1-21 under 35 U.S.C. § 103(a) as being unpatentable over Chang *et al.* (U.S. Patent No. 5,141,744) in view of Bedding *et al.* (WO 94/19940) and Popiel *et al.* (U.S. Patent No. 5,183,950).

The Office asserts that Chang *et al.* teaches a method of protecting plants from insects comprising applying a formulation to the plants. The Office asserts that Chang *et al.* discloses a carrier. (Office Action, page 3, lines 5-7.) Bedding *et al.*, the Office asserts, teaches a formulation comprising entomopathogenic nematodes having a water activity of about 0.85 to 0.99 and carrier being one which maintains water activity when exposed to air at 85 to 100% relative humidity at a specified Celsius temperature for a period of time. (Office Action, page 3, lines 8-11.) The Office asserts that Popiel *et al.* teaches reducing the relative humidity to a range between 50 to 94% for a period of time and for storage and further teach a temperature of 25 degrees Celsius. (Office Action, page 3, lines 12-14.)

The Office admits that Chang *et al.*'s formulation is not the same, but asserts that it would have been obvious to combine the teachings of the cited art to provide for a similar formulation as claimed for use in a method of protecting plants. (Office Action, page 3, lines 15-19.) The Office implies that the elements missing from Chang *et al.*, i.e., the different formulation, are found in Bedding *et al.* and Popiel *et al.*

In response, Applicant respectfully submits that the claims are not obvious in view of the cited art. The Manual of Patent Examining Procedure provides the following guidance for making a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Applicant submits that the Office has not met these criteria in this case.

Chang *et al.* discloses an insecticidal composition in the form of a hydrated macrogel containing an entomopathogen and a hydrated water-retentive compound. Chang *et al.* also discloses applying a combination of nematodes, water-retentive polymer, and gel precursor to a desired site, then inducing gelation by addition of a cation.

Chang *et al.* does not disclose Applicant's specifically claimed formulation, which has a water activity of from about 0.94 to about 0.98, and includes components that maintain the water activity of the formulation at levels of from about 0.94 to about 0.98 when exposed to air at 70%

relative humidity and 25°C for 24 hours. Indeed, the Office recognizes as much, stating that “the formulation used in Chang is not the same [as the claimed formulation].” (Office Action, page 3, lines 15-16.)

Moreover, Chang *et al.* does not provide any insight or direction as to the water-retentive characteristics of the polymer. And more specifically, Chang *et al.* does not provide any guidance as to what water activity is desirable in the formulation. In fact, there is nothing in Chang *et al.* that would teach or suggest that a particular water activity is desirable. Thus, there is nothing in Chang *et al.* that would lead one to consider water activity in choosing components to combine with the nematodes.

Despite this lack of suggestion, the Office concludes that one skilled in the art would have turned to Bedding *et al.* (WO 94/19940) and Popiel *et al.* (U.S. 5,183,950) to modify the teachings of Chang *et al.* In particular, the Office asserts that one would have selected Bedding *et al.*’s entomopathogenic nematode formulation having a water activity of about 0.85 to 0.99 and including a carrier that maintains water activity when exposed to air at 85 to 100% relative humidity for a specified temperature for a period of time. (Office Action, page 3, lines 8-11.)

With regard to Bedding *et al.*, Applicant notes that the inventive formulations have a water activity of 0.94 to 0.99, not 0.85 to 0.99 as cited by the Office. Applicant’s formulation maintains its water activity when exposed to 70% relative humidity at 25°C for 24 hours, not 85 to 100%, as cited by the Office.

In fact, if Bedding *et al.* is read in its entirety, it is clear that it discloses a method of *packaging* entomopathogenic nematodes for *storage*. Bedding *et al.*’s object is to provide a method by which third stage juvenile entomopathogenic nematodes can be packaged for

transportation and storage for prolonged periods at a temperature of about 23°C without the need to constant or periodic attention. (Page 3, lines 17-23.) Bedding *et al.* states that its objective is achieved by packaging the nematodes and a suitable carrier material, after achieving anhydrobiosis of the nematodes, within a polymeric envelope or wrapper. (Sentence spanning pages 3-4.) For transportation, the packages containing the nematodes are placed in a container, along with an element (preferably partially hydrated polyacrylamide) that maintains the relative humidity around the packages in the range of 85 to 100%. (Page 4, lines 3-13.)

In more detail, Bedding *et al.* notes that anhydrobiosis is induced by reducing the water activity of the nematodes in their carrier, preferably to 0.97, which corresponds to an external relative humidity of 97%. (Page 4, lines 14-19.) Bedding *et al.* notes, however, that if water activity falls below 0.8, the nematodes are likely to die. (Page 4, lines 24-27.) Thus, “the storage of the nematodes after they have been wrapped by the method of the present invention *requires* the maintenance of a relative humidity in the storage environment of between 85 per cent and 100 per cent, preferably between 95 per cent and 99 per cent.” (Sentence spanning pages 4-5, emphasis added.)

Thus, when read in its entirety, it is clear that Bedding *et al.* discloses an entire system, including a container, which maintains a relative humidity at 85 to 100%, and more preferably 95 to 99%. Bedding *et al.* does not suggest that its system would allow nematode survival at a relative humidity of 70% at 25°C for 24 hours. There is nothing in Bedding *et al.* that suggests that nematodes could survive in its system without a humidifying element that raises relative humidity to over 85%. Thus, there is nothing in Bedding *et al.* that would lead to selection of a formulation that allows nematode survival at a relative humidity as low as 70%, for any temperature or period.

The Office also relies on Popiel *et al.* to satisfy the deficiencies left by Chang *et al.*, but Popiel *et al.* also fails to satisfy those deficiencies. It appears that the Office relies on Popiel *et al.* for teaching a process for enhancing survival of nematodes in a relative humidity range of between 50 and 94% at 25°C for some period. Applicant respectfully submits that Popiel *et al.* does not support the obviousness rejection.

Popiel *et al.*'s process has two essential steps: 1) removal of surface water, and 2) induction of anhydrobiosis. (Column 7, lines 18-20.) The second step involves subjecting the nematodes to 97±2% relative humidity for some period of time sufficient to induce anhydrobiosis. (Column 7, line 52 - column 8, line 27.) Anhydrobiosis can be induced by exposure to a chamber where relative humidity is controlled by sulfuric acid/water mixtures of the appropriate concentration, or by exposure to environmental chambers of preconditioned humidity. Upon achieving anhydrobiosis, Popiel *et al.* suggest that relative humidity can be reduced for storage, for example, to 50-94% if desired. (Column 8, lines 30-37.)

However, in none of these steps is it suggested that the nematodes be combined with a substance that maintains the water activity of the formulation at a level of between 0.94 and 0.98. Rather, Popiel *et al.* appears to induce anhydrobiosis simply by reducing the relative humidity of the vapor surrounding the nematodes. There is no suggestion in Popiel *et al.* that anhydrobiosis be induced by placing the nematodes in a solution with a lower water activity, or that anhydrobiotic nematodes be placed in a solution with such substances. There is simply nothing at all in Popiel *et al.* that would suggest the use of a substance as claimed by Applicant.

Such a substance is a required element of Applicant's claimed formulation. The Office has admitted that Chang *et al.* does not disclose Applicant's claimed formulation, and Applicant respectfully submits that Popiel *et al.* does not disclose the elements missing from Chang *et al.*

To summarize, Chang *et al.* does nothing to teach or suggest the use of a substance imparting a particular water activity to the formulation. Bedding *et al.* teaches maintenance of a high water activity, but appears to maintain that high water activity through use of a high-humidity container. There is nothing in Bedding *et al.* that would suggest the use of a substance that maintains a specific water activity if relative humidity is as low as 70%. And Popiel *et al.* maintains a specific water activity, but also does so by controlling the humidity of the environment. Popiel *et al.* does not teach or suggest the use of a substance for maintaining the desired water activity. Thus, there is nothing in any of the cited documents, alone or in combination, that would motivate one of skill in the art to make changes to any of the teachings so as to arrive at Applicant's claimed invention, or to combine the teachings so as to achieve Applicant's claimed invention.

Moreover, even if the teachings were combined, the present invention would not result. None of the cited documents, alone or in combination, teach a substance for controlling the water activity at about 0.94 to about 0.98 when exposed to a relative humidity of 70% at 25°C for 24 hours. The Office admits that Chang *et al.* does not teach it. Bedding *et al.* teaches controlling humidity at 85 to 100%, and does not suggest any substance for controlling water activity at a lower relative humidity. Popiel *et al.* apparently achieves the desired water activity without relying on any additional substance. Thus, none of the cited documents provides this missing element of the claims.

Finally, as elements of Applicant's claim are missing from the cited documents, there is no reasonable expectation of success in their combination. Even viewed in a light most favorable to the rejection, there is no reason to believe that a formulation could result that would

survive at 70% relative humidity at 25°C for 24 hours. Absent the claimed elements, there is no reasonable expectation of success in the combination of teachings.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully submits that the claimed invention is not obvious in view of the cited art. Applicant respectfully requests the reconsideration and re-examination of the pending claims. If any action can be taken to expedite issuance of a Notice of Allowance, or to otherwise reduce issues in this case, the Office is invited to contact the undersigned attorney.

Respectfully submitted,

Date:

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